Lumbar canal diameter and walking distance in patients with lumbar spinal stenosis: A multivariate prediction model

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SYNOPSIS SUBMITTED

To

Maharishi Markandeshwar (Deemed to be University)

Mullana, Haryana, India

In partial fulfillment of the requirements for the degree

Doctor of Philosophy

(Physiotherapy)

SUBMITTED

By

GURJANT SINGH

Roll No: 202002

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MULLANA-AMBALA, HARYANA

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This is to certify that the thesis synopsis on, **"Lumbar canal diameter and walking distance in patients with lumbar spinal stenosis: A multivariate prediction model"** has been done by Gurjant Singh under our supervision. We are satisfied with the work presented by the candidate towards the partial fulfillment of Doctor of Philosophy (PhD) in Physiotherapy.

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INDEX

S.No.	CHAPTERS	Page No.
1.	Abstract	**1**
2.	Introduction	**2-4**
3.	Review of literature	**4-16**
4.	Methodology	**16-21**
5.	References	**22-26**
6.	Annexures	**i-x**

Abstract

Introduction: Neurogenic claudication (NC) is the classic clinical presentation of patients with Lumbar Spinal Stenosis (LSS). These patients may or may not present with symptoms of leg pain and difficulty in walking. These symptoms are exacerbated while walking and standing and are eased by sitting or bending forward.

Method: Patients with LSS (having canal diameter 8mm-12mm) at the level of L4 and below will be recruited from the Orthopaedic Physiotherapy OPD of MMIPR, Mullana, Ambala, Haryana. The demographic characteristics and anthropometrics of each subject will be noted and the testing procedure will be explained. Canal diameter will be documented with the help of an MRI. A self-paced walking test will be used to assess the walking distance.

Results: Depending on the normality of the data, Pearson correlation coefficient (r) or Spearman rank correlation coefficient (ρ) will be used to find the correlation between canal diameter at different lumbar levels and walking distance in patients with LSS. Stepwise multiple regression analysis will be done to find the best predictor variables for the dependent variable, canal diameter.

Discussion: The study might help estimate the pain-free walking distance according to the diameter of the lumbar canal at different lumbar levels.

Keywords: Lumbosacral region; magnetic resonance imaging; pain; stenosis; treadmill.

1. INTRODUCTION

Lumbar spinal stenosis (LSS) is defined as the progressive narrowing of the spinal canal (an opening in each vertebra through which the spinal cord passes) causing compression of nerve roots. It is the nerve compression syndrome consisting of compression of nerve roots, dural sac, and spinal cord.[1] LSS is a common disorder diagnosed in 13%-14% of individuals consulting for back pain.[2] The normal diameter of the Lumbar spinal canal ranges between 15-27mm, the diameter less than 12 mm is considered as stenosis.[3] Magnetic Resonance Imaging (MRI) is routinely used in clinical practice to diagnose LSS. Measurements of spinal canal diameter are better measured by MRI.[3,4] With the increase in age, the prevalence of LSS increases, being prevalent as 9.3% in general population and as high as 47% in people older than 60 years of age.[5] In the age group of 65 years and higher, LSS is the most common cause of lumbar spine surgeries.[1,6]

The classic clinical feature of LSS is Neurogenic claudication (NC).[5] The symptoms of NC are described as pain, paraesthesia or cramping, numbness, and weakness in calf, thighs, or buttocks. These symptoms are exacerbated while walking and standing and are eased by sitting or bending forward.[7] Anatomically, the spinal stenosis can occur centrally, within the lateral recess, at the level of the intervertebral disc or in the foramen. The compression of the traversing nerve root occurs in Lateral recess stenosis.[8] LSS can be congenital or acquired or result from a combination of congenital and acquired. In Congenital type, etiology is the presence of short pedicles as in achondroplasia, and acquired type primarily consists of degenerative diseases changes causing narrowing of the canal and leading to compression of nerve roots. [9,10]

As a result of the narrowed lateral and central vertebral canal in the lumbar spine, the lumbosacral nerve roots may get compressed. This physiological dysfunction is responsible for the pathogenesis of NC. The altered mechanics may also develop as a result of ischemia of nerve roots and/or degenerative changes in the spine. This leads to limited walking ability thus causing functional impairment in a patient with NC.[10,11] To mark the Walking Distance (WD), Self-paced walking (SPW) could be a standardized method, being an inexpensive, feasible and reproducible measure to assess the walking capacity in patients with LSS.[12] Also, it ensures a more practical functional assessment as compared to treadmill, as the older population of India may not be familiar to treadmill walking. An X-ray may indicate some degenerative changes in the lumbar spine, and clinical assessment findings may direct the clinician to the possibility of stenosis. But, for the confirmatory diagnosis of stenosis, radiological investigations are must. The normal diameter of lumbar canal ranges from 15mm-27mm, canal diameter less than 12mm is termed stenosis. Decreased WD is the primary complaint of patients with LSS. There are various studies that emphasized on the decreased WD in LSS, no literature has presented the impact of change in canal diameter on WD, and there is the need to have some predictive data, by which, clinicians can have an estimated walking distance according to the diameter of lumbar canal at most stenotic level.

1.1. RESEARCH QUESTION:

Does the walking distance depend on canal diameter? And how much does the change in canal diameter affects the distance of walking in patients with LSS?

1.2. AIM OF STUDY:

To measure the WD and developing the multivariate prediction model for WD with stenosis at different lumbar levels in patients with LSS.

1.3. OBJECTIVES OF THE STUDY:

1.3.1. To find distance of walking with stenosis at following lumbar levels:

1.3.1.1. L_3-L_4

1.3.1.2. L_4-L_5

1.3.1.3. L_5-S_1

1.3.2. To do the regression analysis of walking distance at different lumbar levels.

2. REVIEW OF LITERATURE

2.1. Lumbar spinal stenosis (LSS)

Lumbar spinal stenosis can be termed as narrowing of the diameter of the central canal intervertebral nerve root foramina, or lateral recesses.[13] It may be symptomatic or non-symptomatic. Age-related degenerative changes are one of the leading causes of LSS. Narrowing of the spinal canal may occur due to other conditions like degenerative spondylolisthesis and degenerative scoliosis.[14] Neurogenic Claudication is a clinical syndrome that is presented as a typical clinical presentation of LSS.[7]

A retrospective hospital-based study was conducted in patients with LSS among the population of Sudan. 101 patients were included in the age group between 15 to 80 years in the study and determined the clinical presentation of LSS in them. The results of the evaluated that male patient above the age of 51 years i.e 40.6 % of the total study population were mostly affected. Therefore, the study highlighted lower limb numbness, followed by pain and weakness as clinical features of the LSS. Moreover, About 84.2%,

had low back pain that exaggerates with activities like, walking or standing. Lower pain was observed in about 93% of individuals with symptoms involving the entire leg.[5]

2.2. Etiology of LSS

LSS is a degenerative condition, which may persist for years without any symptom. LSS can be divided into primary and secondary according to etiology. Primary or congenital LSS is caused by congenital abnormalities and secondary or acquired LSS is a consequences due to degenerative changes such as facet joint hypertrophy and hypertrophy of ligamentum flavum, decrease in vertebral disc height, spondylolisthesis, herniated disc that leads to compression of nerve roots.[8] In the chain of events, Degenerative disc disease can be the initial occurrence. With the degeneration of endplates, nutrition diffusion decreases, which promotes disc degeneration. It further contributes to decreased disc heights, altered spine biomechanics, facet arthropathy, spondylosis, osteophytes formation, and spinal stenosis.[15]

2.3. Pathophysiology of LSS

LSS is defined as a condition with diminished space available for the neural and vascular structures owing to degenerative changes in spinal canal. The spinal canal narrowing could be present since birth (Congenital spinal stenosis) or may have occurred due to hypertrophy of ligamentum flavum, disc degeneration, facet joint hypertrophy or all among the mentioned causes (degenerative spinal stenosis).[16] LSS can be classified on the basis of location of compression of neural element i.e central or lateral spinal stenosis. The hypertrophy of ligamentum flavum leads to central stenosis, whereas facet hypertrophy associated with osteophytes would lead to lateral stenosis. Also the LSS can be defined as mild, i.e decrease of one third of the space

decreased for the neural structures, or defines as moderate i.e one third two third of the space decreased for the neural structures or severe i.e more than two third space reduced for the neural structures available in spinal canal. It can be seen in radiological findings.[17] The narrowing of the central canal and lateral spinal canals results in compression of spinal nerves and thus causing ischemia of spinal nerves.[18] This compression on the anatomic structures passing through the central or lateral canal results in the appearance of symptoms like constriction of blood supply to the cauda equina.[11]

2.4. Prevalence of LSS

An observational cross-sectional study on residents of city of Framingham has conducted a study to find out the prevalence of acquired and congenital LSS seen on CT scan in a general sample and also to find out the relation between low back pain and LSS. In this study, 3259 patients went through a CT scan and among them, 191 patients were recruited and using a self-report questionnaire for low back pain which preceded 12 months was evaluated. Acquired and congenital LSS was differentiated using 2 cut points which were 12mm and 10 mm for relative and absolute LSS respectively. The relation between low back pain and LSS was examined by using multiple regression. Congenital group included 4.7% of patients with relative LSS and in 2.6% absolute LSS. In acquired LSS there were 22.5% and 7.3% respectively. The prevalence of absolute and relative LSS was 4.0% and 20.0 % respectively. Acquired LSS was seen with increased prevalence with age <40 years and the presence of absolute LSS was related to low back pain.[19]

A study conducted in 2018 was conducted in Thailand to evaluate the characteristic of osteophyte around the lumbar vertebral foramina in patients with LSS. 179 individuals were included in the study of 31 to 90 years. They have divided the lumbar vertebrae into three zones i.e laminar zone, pedicle zone, and posterior body with further division of laminar and pedicle zone into left and right and the posterior body was divided into the superior and inferior part and have also observed a positive association between these vertebral foramina of all levels and age. They concluded that the osteophytes formation was the highest prevalence in the inferior posterior body zone in the lumbar vertebrae (L1- L4) and superior vertebrae body zone in L5 vertebrae. These changes are related to age as more cumulative force is loaded over the posterior body, Though vertebral osteophytes can develop at age of 21, changes are more distinguishable after 51 years of age.[20]

2.5. Clinical Presentation of LSS

An Observational Correlation study analysed the Dynamic plantar pressure in 20 patients with Lumbar spinal stenosis (L4-L5 level) before and after neurogenic intermittent claudication. Patients within the age group 56- 73 years were included in the study. Anthroprometric data, foot length, and T-score of body mineral density were collected for comparison. The scientific Footscan software was used to divide the foot into different areas and to scan the pressure at foot to analyze the plantar pressure. The study concluded that there was a forward flexion posture while walking leading to a shift in the Centre of gravity anteriorly and increasing chances of forwarding fall and higher risk of strain or overuse injuries of foot in patients with LSS.[1]

A prospective observational study in European population with the intervention was conducted to evaluate the severity of LSS and pelvic stability during walking. The patient above the age of 40 years with degenerative spinal stenosis was included in the study. Pelvic rigidity during walking was assessed using a 6-minute walk test as the inertial sensors are placed on the pelvis overlying L5. The study concludes that pelvic rigidity is seen in patients with LSS in order to keep the spinal canal more open as a compensatory mechanism to reduce pain.[6]

Clinical features and clinical tests along with radiographical reports are used to form an actual diagnosis of Neurological claudication (NC). A Questionnaire survey of physiotherapists was conducted to find out the awareness of Neurogenic Claudication (NC), assessment pattern of the patient, and current management of patients with NC among the clinical practitioners within large primary care-based musculoskeletal service in the UK. The study included 54 physiotherapists, they were given the questionnaire out of which 50 filled it and returned the questionnaire. According to the responses for subjective history taking in patients with NC revealed that according to almost the majority of respondent posture affects the symptoms the most as it increases with walking and standing and is reduced during sitting posture or stooping. Other history-taking responses suggested the symptoms in the lower limb include cramps, paraesthesia, heaviness, and sensory changes, and long-standing low back pain. A large population of respondents about 58%, suggested that if with the lumbar extension the symptoms are aggravated it would increase the suspicion of NC. Around 22% reported that a stooped standing posture and flattening of lumbar lordosis along with radiographically is suggestive of NC. Many respondents suggested that NC can be

differentiated by vascular claudication by its postural assessment, as the change in posture influences the symptoms of NC and not that of vascular claudication. The majority of respondents suggested the physiotherapy treatment for NC including flexion-based exercises and trunk muscle stabilization exercise. The study concluded that the neurological claudication is recognized as posture related to clinical syndrome and patient education is the major part of the treatment of NC.[7]

2.6. CANAL DIAMETER ASSESSMENT

In the lumbar spinal canal, the normal canal diameter varies from 15mm - 27mm. If this Lumbar spinal canal diameter gets reduced to less than 12 mm due to any pathological or degenerative changes and is known as LSS.[21]

The evaluation of spinal canal stenosis (SCS) can be done with the help of Magnetic Resonance Imaging (MRI) by measuring the narrowing of the canal diameter. A study done in 2011 found that asymptomatic patients may also represent a narrowing of the spinal canal. It was a longitudinal comparative type study conducted on 59 patients out of which their 43 were symptomatic while 16 were asymptomatic healthy adults. Both male and female patients within the age group of 20- 70 years of age were included in the study. Any case of trauma, cyst, neoplasm, disc displacement or herniation and any postoperative cases were excluded from the study. Anteroposterior diameter, transverse diameter, and cross-sectional area all three parameters are considered to find out any deviation from the normal value. In the result of the study, out of 43 symptomatic cases, 14 cases complaint only of back pain, 12 cases presented with unilateral leg pain, pain in both legs was present in 6 and 11 cases were having back pain along with leg pain and leg weakness. According to this study, it was found that the

canal stenosis was less common at L1 and L2 levels, and the possibility increases as we go towards Lower lumbar levels i.e. L3-S1.[9] Another study on Canadian population has found that LSS is more prevalent at L_4-L_5, followed by L_3-L_4 and L_5-S_1.[22]

Though MRI has been proved to be reliable to measure canal diameter narrowing, the patients with LSS may be asymptomatic and may not show the neurological symptoms of LSS therefore, MRI cannot alone prove the diagnosis. An observational prospective study was conducted on 100 patients and lumbar canal diameter was measured with the help of MRI. Out of 100 patients, 45 were females and 55 were males with the age group of 20-30 years, 60 patients had low backache and the rest 40 didn't have low backache. This study was aimed to compare lumbar canal diameter in person with and without low back pain with LSS, diagnosed using MRI. It was found that 41 patients were stenosed in symptomatic cases. In 5 cases there was stenosis in all 3 levels. In 6 patients stenosis was seen on L3-L4 and L4-L5.In 22 cases L4-L5 and L5-S1 stenosis was noticed. In 8 cases stenosis was seen in L3-L4 and L5- S1 levels. In 5 cases stenosis was seen at all three levels and in two patients it was seen at L3-L4 and L5- S1 levels in persons without low back pain. Thus, this study concluded that even a patient with low back pain had a normal canal diameter in 19 cases and canal narrowing was seen in an asymptomatic case. A normal cross-sectional area was seen in most symptomatic patients. Thus this study proves that along with MRI scan, detailed clinical examination and history helped to make an actual diagnosis.[3]

A correlation study was conducted to determine the degree of clinical manifestation and the radiographical images in patients with neurogenic claudication and center LSS. Eighty-four patients with an average age of 70 years were included in

the study. Magnetic resonance imaging (MRI) was used to evaluate the stenotic level and extent of the narrowing of the spinal canal. The results of the study show a correlation between the MRI findings describing central canal stenosis and the symptoms of the patients. The study concluded that the radiological severity of LSS (i.e more central stenosis) is related to more pronounced neurologic impairment in the lower extremities. But no association was found between radiological findings, degree of stenosis and functional disability, and walking ability.[23]

2.7. Neurogenic claudication

A study was conducted in Turkey, to evaluate the change in F wave study prior and immediately after walking in patients with Neurogenic Claudication (NC).In this study, 26 patients with LSS were recruited who had symptoms and signs of NC and 20 healthy volunteers were. F wave study of the tibial nerve, sensory, and motor nerve conduction was done in both the groups. Exercise treadmill protocol was used for the patients and the time of the appearance of the symptom and total ambulation time was recorded and the tibial F wave study was repeated immediately after stress walking. There was a significant increment in F wave values in both the legs inpatient group but not in control participants. Hence, this study concluded that F- wave study after walking, it provided more information regarding, NC.[13]

2.8. Walking tolerance

A 2- phase study conducted was by Comer et al in UK, Europe in 2010 on the participants aged 50 and older determine the immediate effects of using a stick on the walking tolerance and its effectiveness of the daily use of the walking stick in the improvement of the symptoms and daily functions in the patients with Neurogenic

Claudication (NC). It was a randomized trial in which 46 patients (24 female, 22 men) with unilateral NC were included. In this study, the experimental group was provided with a walking stick and the control group was not, then the walking tolerance was compared using a shuttle walk test. No significant improvement was found in the symptom severity score and a physical function scale score of the Zurich Claudication Questionnaire between the two groups. Thus this study concluded that there is no improvement in posture, symptoms, and function in participants using a walking stick.[24]

2.9. Walking Distance

To get a criterion measure to assess the walking capacity in patients with LSS, a validation study was done. The objective of the study was to develop and examine the reproducibility of a criterion measure of walking capacity, and to use it to examine the validity of treadmill walking method in patients with LSS. In this study, the Self-Paced Walking Test was developed and the test-retest reproducibility of it was examined. For the study, 45 patients of LSS with mean age of 66.9 ± 9.6 years were included. Treadmill walking included the speed of 1.2m/hr at 0^0 inclination. Whereas, SPWT protocol included walking over a 200m indoor track until they had to stop due to pain or for a maximum of 30 minutes of walking. The study concluded that, SPWT is a feasible and reproducible criterion to assess the walking capacity in patients with LSS. A systematic bias was observed as the patients walked further as compared to treadmill walking.[12]

A Prospective study was done to determine the functional status in the patients with symptomatic LSS. This study included thirty-eight patients with a median age of 69.3 ± 7.9 years. 6-minute walk test was used as an outcome measure, patients were

first asked to verbally evaluate the walking perimeter, and then it was evaluated by a 6-minute walk test at a self-selected speed. Patients were asked to cover the distance up to 500 m, 21 patients were able to walk up to 500 m. Walking perimeter and walking speed were used to assess the functional capacity.[2]

An analysis study evaluated the retest reproducibility of walking test in patients with LSS. Seventy patients with LSS evaluated leg numbness and leg pain. The walking test was performed from 0 to 4 weeks. Among walking tests, stoop tests, cycling tests, and treadmill tests this study assessed the walking test as a superior test for assessing the LSS with an ICC value of 0.67. It has also shown better results in showing acceptable reproducibility of walking tests.[20]

The evaluation of intermittent claudication can be done based on objective and subjective parameters. One of the established methods includes determination of the walking distance on the treadmill, which measures both the Initial Claudication Distance (ICD), the initial distance at which the patient feels pain, and Absolute claudication distance (ACD), a distance that denotes the maximum distance at which the patient feels pain and stops walking due to pain. A study was conducted on 52 patients who had the peripheral arterial occlusive disease. This study compared the association and practicability of graded treadmill protocol versus a single stage in the assessment of the absolute claudication distance. The graded exercise test and constant load test were carried out randomly on the same day with standard conditions. In constant test (C-test) the treadmill gradient was set at 12% and a constant speed of 3km/h then ICD (Initial Claudication Distance) and ACD (Absolute Claudication distance) distance were determined. In the Graded exercise test, initially patient walks at 0% gradient on the

treadmill at a constant speed of 3km/h. The gradient was gradually increased each time after an interval of 3min until it reached up to 17.5%. This study concluded that the C-test would be more suitable in the assessment of ACD.[25]

A study was conducted to find reliability and validity to measure the distance at which the patient stops walking due to claudication pain. In this study, they included patients with intermittent claudication who were following a supervised exercise program according to the guidelines of the Royal Dutch Society of a physiotherapist for 3 months or more and excluded patient who had cardiopulmonary co-morbidities or give a reason other than Intermittent claudication that may result in discontinuation of the treadmill test. This study was divided into two parts. The first part included 57 patients who performed two standardized treadmill test. The first part determined the reliability of FCD. 25 patients were included in the second part of the study who performed standardized treadmill test and Rand- 36 questionnaire and these data were used to determine the validity of FCD, ICD, and ACD. The FCD correlated significantly with five out of nine domains, namely physical function physical role, vitality, pain, and health change. Thus this study concluded that FCD is a reliable and valid method to measure the functional capacity in trained patients with intermittent claudication and therefore reflecting that FCD is a better measure for actual functional impairment.[26]

2.10. Quality of life

Patients with LSS have a psychological impact of Neurogenic Claudication (NC) due to reduced walking distance leading to functional impairment. A semi-structured interview via telephone was conducted on 28 patients to find out the problem which was mostly bothering the patients with NC. Its impact on their day to day life was noted and their

expectations non-surgical and surgical treatments. Patients with NC have limited walking distance was a distinct functional limitation and its impact on social and recreational activities. Significant emotional effects were noted among patients with NC. This study concluded that a patient's perspective about NC had a significant effect on pain, and limitations with walking and also affects the emotions of an individual. Therefore affecting the Quality of life of the patient with NC.[27]

A prospective cohort study was done to assess the outcomes of treatment of nocturnal leg cramps following conservative treatment and comparing the outcome of the treatment with historical cohorts treated surgically the other purpose to conduct this study was to observe the variations of patterns concerning the site of and time of occurrence. In this study sixty-one, symptomatic patients with Lumbar spinal canal stenosis (LSCS) were included in Group I and in Group II 46 patients were included in the control group selected from the general population. A questionnaire was used for low back pain. The findings of this study confirmed that there is a higher prevalence of Nocturnal leg cramps in the older population with LSCS. These nocturnal cramps have a minimal negative impact on the quality of the patient with LSCS which could be managed conservative treatment. (to be cited, nishant chhabra et al, nocturnal cramps in patients with LSS)

The Short Form 36 Health Survey Questionnaire (the SF-36)[28,29] is used to indicate the health status, it was developed in the USA. A survey study was conducted to test the reliability and construct validity of the SF-36. This study compared the Wales norms. The data was collected by a combination of methods. Letters were sent to all the selected addresses to explain the purpose of the Welsh health survey (WHS) and face

to face interview were taken to collect household data (including data for SF-36) for each adult above 16 years of age. The SF-36 is a 36 item scale that measures eight domains of health status and the score ranges from 0 to 100 where 0 denotes worst health status and 100 denotes the best health status of an individual. The results of this study showed that the health scores deteriorate with advancing age. The test performed on SF-36 dimensions proved the SF-36 scale to be reliable and has content validity, and thus showed SF-36 as a useful tool for measuring health status and the quality of life of an individual.[28]

3. METHODOLOGY

3.1. Study design

A cross-sectional study.

3.2. Study location

Orthopaedic Physiotherapy OPD, MMIPR, Mullana, Haryana.

3.3. Study setting

The study will be conducted inside the Research lab of Maharishi Markandeshwar (Deemed to be University), Mullana-Ambala, Haryana.

3.4. Study participants

The study will be performed on patients with LSS.

3.5. Sampling Design

Purposive sampling.

3.6. SAMPLE SIZE ESTIMATION

Sample size was calculated using the sample size calculation formula, $N= [(Z\alpha+Z\beta)/C]^2 + 3$. Where, $Z\alpha= 1.96$; $Z\beta= 0.8$; and $C= 0.5 \times \ln [(1+r) / (1-r)]$. Value of correlation

coefficient (r= 0.51) was taken from a previous study.[30] Thus, using the above mentioned sample size calculation formula, minimum sample size was calculated as N= 36. So, minimum 36 samples will be recruited for each lumbar level, by which, minimum total sample size calculated will be 108.

3.7. Selection criteria

3.7.1. Inclusion criteria

- Both male and female patients with an age group of 45-70 years.
- Patients with LSS at different lumbar levels
- Patients with lumbosacral degeneration
- Patients with symptoms of neurogenic claudication

3.7.2. Exclusion criteria

- Previous History of trauma or fracture in past 6 months
- Any congenital or acquired deformity of spine
- Postoperative case of surgery or laminectomy at lumbar region

3.8. STUDY DURATION: The minimum duration will be 2 years including the formation of the research question, application, collection, data analysis, and reporting.

3.9. MATERIALS TO BE USED FOR DATA COLLECTION

- Cone markers
- Measuring Wheel
- Weighing machine
- Measuring tape

3.10. Outcome Variables

- Lumbar canal Diameter (MRI)
- Walking Distance (SPW)

3.11. PROCEDURE:

3.11.1. ETHICAL STATEMENT:

Ethical approval of this study will be taken from the Institutional Ethics Committee of Maharishi Markandeshwar (Deemed to be University). The study will be done in accordance with the Helsinki declaration revised in 2013 and the National Ethical Guidelines for Biomedical Research involving Human participants, 2017.

3.11.2. RECRUITMENT

The study will be a cross sectional study. Male and female patients with symptoms of neurogenic claudication will be recruited for this study. Sampling will be done by the method of purposive sampling. The written consent form will be taken from the recruited patients for their voluntary participation. The entire demographic characteristic such as age, gender, weight, height, limb length, waist circumference and hip circumference of each patient will be noted. Canal diameter will be documented with the help of an MRI. The SPW will be done to find the WD for each patient.

3.11.3. PROTOCOL

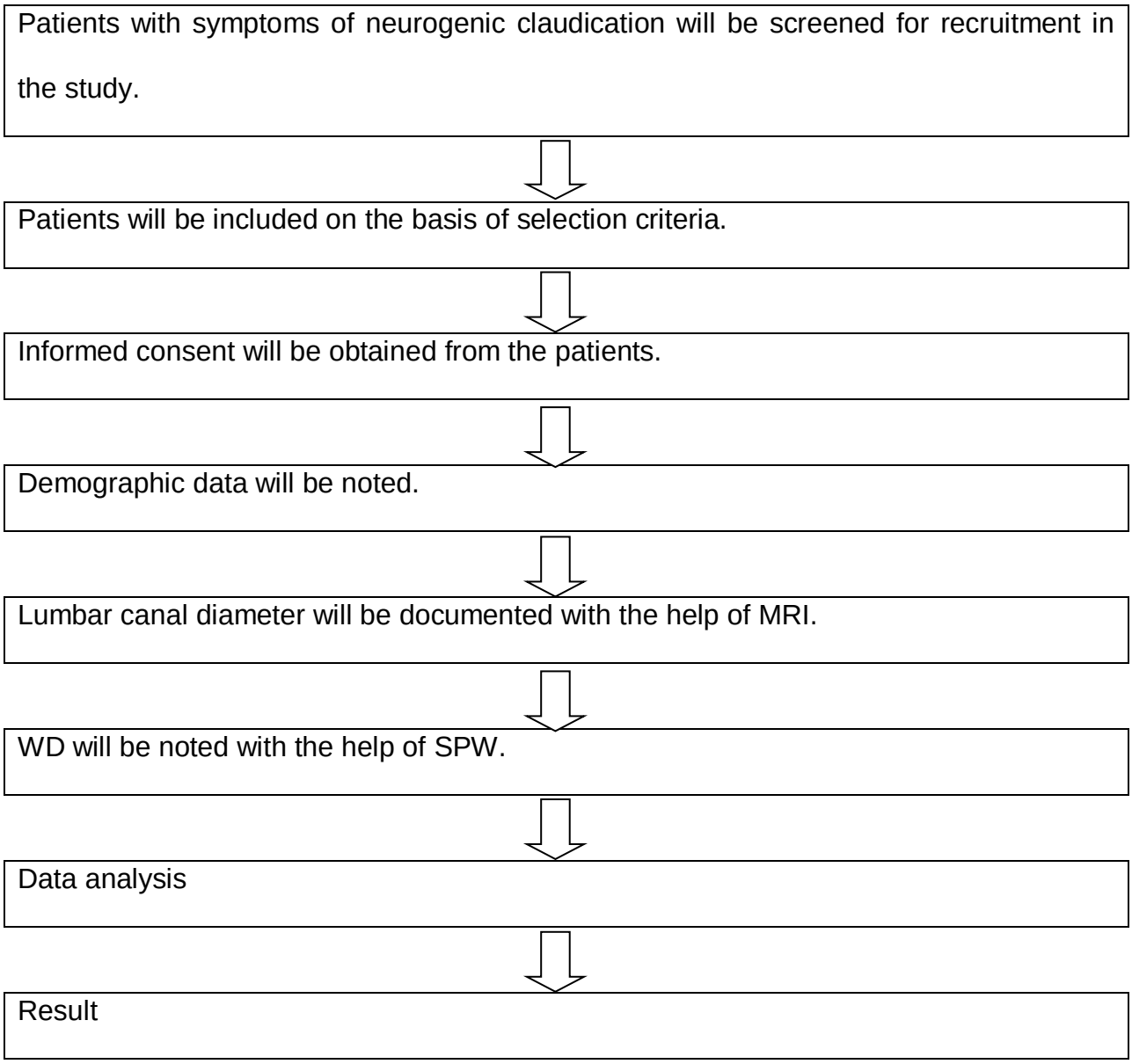
Patients with symptoms of neurogenic claudication will be screened for recruitment in the study.
Patients will be included on the basis of selection criteria.
Informed consent will be obtained from the patients.
Demographic data will be noted.
Lumbar canal diameter will be documented with the help of MRI.
WD will be noted with the help of SPW.
Data analysis
Result

Figure.1 – Flow chart to show the protocol

3.12. METHODS OF DATA COLLECTION:

The anthropometric data will be collected by the primary researcher from the out patients department of recognized hospital.

3.12.1. Lumbar Canal Diameter

After the initial screening of the patients for the inclusion in the study, the patients exhibiting the clinical features of LSS will be asked for an MRI. MRI will be done by an experienced radiologist, who will be blinded to the walking distance of the patients. MRI will be done through 1.5 T Philips Multiva Magnetic Resonance Imaging system, and the imaging sequences, Sagittal T_1, Sagittal T_2, Coronal STIR, Axial T_1, and Axial T_2 will be included. Antero-posterior canal diameter of 12mm or lesser at the most stenotic level from L_3 and below will be noted.[5]

3.12.2. Walking Distance

Self-Paced Walking will be used to measure the walking distance.[12] Before measuring the WD, patients will be informed about the procedure and informed consent will be obtained. Safety related to floor walking will be ensured by eliminating slippery surface or footwear of the patients. Each patient will be asked to walk in their own pace continuously over a marked track of 30m as far as possible without any discomfort due to pain. Track marking will be done with the help of marking cone. The physiotherapist will follow the patient with approximately 1m distance behind the patient to eliminate the risk of fall. WD will be measured with the help of measuring wheel. The distance (meters) where patients will prefer to stop due to pain, will be noted for each patient.

3.13. DATA ANALYSIS:

Statistical analysis was done using statistical package for social sciences (SPSS), version 16 (SPSS Inc. Chicago, IL, USA). A significance level of 0.05 will be set. The normality of the data will be determined by Shapiro-Wilk or Kolmogorov Smirnov test, depending upon the sample size. Depending on the normality of the data, Pearson correlation coefficient (r) or Spearman Rank correlation coefficient (ρ) will be used to find the correlation between canal diameter at different lumbar levels and walking distance in patients with LSS. Stepwise multiple regression analysis will be done to find the best predictor variables for dependent variable, canal diameter. Percentage of total variance in the canal diameter, accounted for by the predictor variables, will be expressed as adjusted square of the multiple correlation coefficient (R^2).

3.14. CLINICAL IMPLICATION

The study might be helpful clinically in the prognosis of the condition and to have an estimated pain free walking distance according to the diameter of the lumbar canal. The conservative treatment may be planned keeping the FCD into consideration, so as to avoid exertion beyond the proposed distance in designing a home protocol for the patients; or combining it with a period of rest after specific exertion.

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Annexure-1 (a)

Information Sheet

Title of Study- Lumbar canal diameter and walking distance in patients with lumbar spinal stenosis: A multivariate prediction model

Name of Principal Investigator- Gurjant Singh, MPT, (PhD)

Institute- M.M Institute of Physiotherapy and Rehabilitation, Maharishi Markandeshwar (Deemed to be University), Mullana-Ambala, Haryana.

Under the Guidance of- Dr. Asir John Samuel, MPT, PhD (Physiotherapy), Associate Professor, MMIPR, MM (DU), Mullana-Ambala, Haryana

Under the Co-guidance of- Dr. Manjeet Singh, MS (Orthopedics), Professor & Head, Department of Orthopedics, MMIMSR

Type of the study- A cross-sectional study

Purpose of the research

Lumbar spinal stenosis is one of the degenerative conditions leading to back pain and decreased distance of walking due to decrease in diameter of lumbar canal. This study will help in developing a prediction equation for canal diameter and walking distance at different lumbar levels.

Participant selection

We are inviting both male and female patients aged between 45-70 years suffering with back pain and inability to walk due to Lumbar spinal stenosis.

Procedure

After the patient is selected according to the inclusion criteria, baseline measurements will be taken. Canal diameter will be noted with the help of an MRI, and to measure

walking distance, patient will be asked to walk at his/her own pace up to the tolerable distance with respect to pain.

Duration

Patients will be asked for assessment only on the initial day of their visit to physiotherapy OPD, and it may take approximately 10 minutes.

Side Effects

The study has no side effects.

Risks

There may be a risk of fall while walking. To eliminate the risk, physiotherapist will walk at a distance of approximately 1m behind the patient. You may terminate your participation in the study at any time if you choose.

Benefits

The procedures listed above will be advantageous to the participants as it will help in finding the pain free distance of walking for them. Please note that any kind of financial benefits will not be given to the participants for their participation.

Confidentiality

Patient responses to this study will be anonymous. Every effort will be made by the researcher to preserve confidentiality. Photo identity will be preserved by masking the eyes on the photograph. However, full anonymity cannot be assured. Participant data will be kept confidential except in cases where the researcher is legally obligated to report specific incidents. These incidents include, but may not be limited to, incidents of abuse and suicide risk.

Right to Refuse or Withdraw

You do not have to take part in this research if you do not wish to do so and refusing to participate will not affect your treatment at this clinic in any way and all your rights will be respected.

सूचना पत्र

अध्ययन का शीर्षक-

रीढ़ की हड्डी में कनाल का व्यास और लम्बर स्पाइनल स्टेनोसिस के रोगियों में पैदल दूरी: एक बहुभिन्नरूपी अनुमानिक मॉडल

प्रधान अन्वेषक का नाम- गुरजंत सिंह, एम.पी.टी., (पीएच.डी)

संस्थान- एम। एम। इंस्टीट्यूट ऑफ फिजियोथेरेपी एंड रिहैबिलिटेशन, महर्षि मारकंडेश्वर (डीम्ड टू बी यूनिवर्सिटी), मुलाना-अंबाला, हरियाणा।

के मार्गदर्शन में- डॉ। आसिर जॉन सामुवेल, एम.पी.टी., पीएच.डी (फिजियोथेरेपी), एसोसिएट प्रोफेसर, एम.एम.आई.पी.आर., एम.एम. (डी.यू.), मुलाना-अंबाला, हरियाणा।

के सह मार्गदर्शन में- डॉ। मंजीत सिंह, एमएस (ऑर्थोपेडिक्स), प्रोफेसर और प्रमुख, ऑर्थोपेडिक्स विभाग, एम.एम.आई.एम.एस.आर, एम.एम. (डी.यू.), मुलाना-अंबाला, हरियाणा।

अध्ययन का प्रकार- एक क्रॉस-अनुभागीय अध्ययन

अनुसंधान का उद्देश्य

काठ का रीढ़ की हड्डी का स्टेनोसिस अपक्षयी स्थितियों में से एक है जो कमर दर्द के लिए अग्रणी है और काठ के व्यास में कमी के कारण चलने की क्षमता में कमी आ सकती है । यह अध्ययन काठ के व्यास और विभिन्न काठ के स्तरों में चलने की दूरी के लिए एक भविष्यवाणी समीकरण निर्धारित करने में मदद करेगा।

प्रतिभागियों का चयन

हम 45-70 वर्ष की आयु के पुरुष और महिला दोनों रोगियों को कमर दर्द और लम्बर स्पाइनल स्टेनोसिस के कारण चलने में असमर्थता के लिए आमंत्रित कर रहे हैं।

प्रक्रिया

शामिल किए जाने के मानदंडों के अनुसार रोगी का चयन करने के बाद, आधारभूत माप लिया जाएगा। एम.आर.आई की मदद से कनाल व्यास को नोट किया जाएगा, और पैदल दूरी को मापने के लिए, रोगी को दर्द के संबंध में सहनीय दूरी तक अपनी गति से चलने के लिए कहा जाएगा।

समयांतराल

मरीजों को फिजियोथेरेपी ओ.पी.डी. में उनकी यात्रा के शुरुआती दिन ही मूल्यांकन के लिए कहा जाएगा, और इसमें लगभग 10 मिनट लग सकते हैं

दुष्प्रभाव

अध्ययन का कोई दुष्प्रभाव नहीं है।

जोखिम

चलते समय गिरने का खतरा हो सकता है। जोखिम को खत्म करने के लिए, फिजियोथेरेपिस्ट रोगी के पीछे लगभग 1 मीटर की दूरी पर चलेगा। यदि आप चाहेंगे, तो आप किसी भी समय अध्ययन में अपनी भागीदारी को समाप्त कर सकते हैं।

लाभ

ऊपर सूचीबद्ध प्रक्रियाएं प्रतिभागियों के लिए फायदेमंद होंगी क्योंकि यह उनके लिए चलने के दर्द से मुक्त दूरी का पता लगाने में मदद करेगा। कृपया ध्यान दें कि प्रतिभागियों को उनकी भागीदारी के लिए किसी भी प्रकार का वित्तीय लाभ नहीं दिया जाएगा।

गोपनीयता

इस अध्ययन की रोगी प्रतिक्रियाएँ अनाम होंगी। शोधकर्ता द्वारा गोपनीयता बनाए रखने के लिए हर संभव प्रयास किया जाएगा। फोटो मे आंखे पे पट्टी लगकर पहचान को संरक्षित किया जाएगा। हालाँकि, पूर्ण

गुमनामी का आश्वासन नहीं दिया जा सकता है। प्रतिभागियों को उन मामलों को छोड़कर गोपनीय रखा जाएगा जहां शोधकर्ता विशिष्ट घटनाओं की रिपोर्ट करने के लिए कानूनी रूप से बाध्य है। इन घटनाओं में शामिल हैं, लेकिन यह सीमित नहीं हो सकता है, दुरुपयोग और आत्महत्या के जोखिम की घटनाएं।

मना करने या वापस लेने का अधिकार

यदि आप प्रतिभागी नहीं बनना चाहते हैं तो आपको इस शोध में भाग लेने की आवश्यकता नहीं है और भाग लेने से इनकार करने के कारण किसी भी तरह से इस क्लिनिक में आपके उपचार पर कोई असर नहीं पड़ेगा।

Annexure-1 (b)

Consent Form

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant _____

Signature of Participant _____

Date _____

Day/month/year

If illiterate-

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ Thumb print of participant

Signature of witness _____

Date _____

Day/month/year

Name of Researcher/person taking the consent: Gurjant Singh

Signature of Researcher /person taking the consent_____

Date _____

Day/month/year

सहमति पत्र

मैंने पूर्वगामी जानकारी पढ़ी है, या इसे मुझे पढ़ के सुनाया गया है। मुझे इसके बारे में सवाल पूछने का मौका मिला है, और जो भी सवाल मैंने पूछे हैं उनका जवाब मेरी संतुष्टि के लिए दिया गया है। मैं स्वेच्छा से इस शोध में भागीदार के रूप में भाग लेने के लिए सहमति देता हूं।

प्रतिभागी का नाम_____

प्रतिभागी के हस्ताक्षर_____

तारीख _____

दिन/महीने/साल

अगर अनपढ़-

संभावित प्रतिभागी को सहमति फॉर्म मेरी उपस्थिति में पढ़ के सुनाया गया है, और व्यक्ति को सवाल पूछने का अवसर मिला है। मैं पुष्टि करता हूं कि व्यक्ति ने स्वतंत्र रूप से सहमति दे दी है।

गवाह का नाम_____

गवाह के हस्ताक्षर_____

तारीख _____

दिन/महीने/साल

प्रतिभागी का थम्ब प्रिंट

सहमति लेने वाले शोधकर्ता / व्यक्ति का नाम: डॉ। गुरजंत सिंह (पी.टी.)

सहमति लेने वाले शोधकर्ता / व्यक्ति का हस्ताक्षर_____

तारीख _____

दिन/महीने/साल

Annexure-2

Data Collection Sheet

Name-

Age-

Gender-

Address-

Contact number-

Height-

Weight-

Body Mass Index (BMI)-

Waist Circumference-

Hip Circumference-

Limb Length measurement-

Level of Stenosis (most stenotic level)-

Canal diameter (most stenotic level)-

Annexure-3

Plagiarism Report

URKUND

Urkund Analysis Result

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Submitted: 10/19/2020 10:47:00 AM
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